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(71) Sökande Pacesetter AB, Järfälla SE
Applicant (s)

(21) Patentansökningsnummer 9901966-3
Patent application number

(86) Ingivningsdatum 1999-05-28
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Stockholm, 1999-12-10

För Patent- och registreringsverket
For the Patent- and Registration Office


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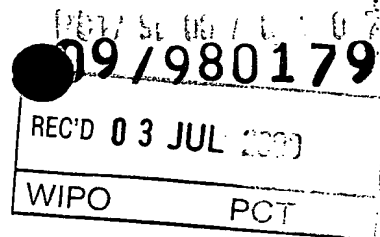
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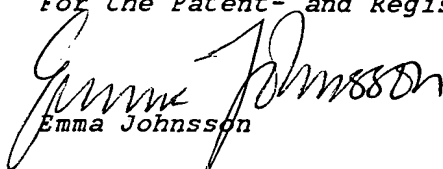
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Implantable heart stimulatorTechnical field of the invention

- 5 The present invention relates to an implantable heart stimulator, e.g. a pacemaker or a defibrillator, according to the preamble of the independent claim.

Background of the invention

10

The purpose of the invention is to improve the detection safety of a heart signal detection means in an implantable heart stimulator.

- 15 In conventional pacemaker technology often a single band-pass filter is used in the sensing circuit of the pacemaker in order to detect electrical heart signals. When using this known technique the origin of a signal that caused a sensed event is difficult to determine.

- 20 A ventricular event occurring early in the heart cycle (prior a normally timed QRS-complex) and arising from a focus in the ventricles is often referred to as a premature ventricular contraction (PVC).

- 25 If a PVC not is detected due to undersensing it can result in that inappropriately timed, asynchronous or competitive stimulation pulses are delivered. Undersensing is defined as a failure of the pacemaker to sense an electrical signal related to a heart event, e.g. a PVC, due to that the sensitivity of the sensing circuit of the pacemaker is too
30 low. This can often be corrected by programming the pacemaker to a more sensitive setting, i.e. decreasing the value of the sensitivity level.

- 35 US-4,880,004 discloses an implantable cardiac stimulator for detecting and treating cardiac arrhythmias. The stimulator includes a sense amplifier responsive to sensed cardiac signals for detecting and distinguishing normal and abnormal

- cardiac activity within the sensed signals. The sense amplifier includes an automatic gain control amplifier, a filter and a comparator having a pair of signal channels for processing the sensed signals according to different
- 5 frequency bandpass characteristics to establish sensing thresholds, margins and signal gain. One of the signal channels constitutes a feedback loop for determining the signal gain and the sensing margin for the other channel.
- 10 In US-5,350,402 an atrial defibrillator is disclosed including a first detector for detecting R-waves of the heart and a second detector for detecting T-waves of the heart. The detection criterion is based on a predetermined time interval relationship between the R-wave and the T-
- 15 wave. According to a software implementation of the T-wave detector a microprocessor may be implemented for filtering the output of a sense amplifier with a high-pass filter and a low-pass filter. The derivative of the filtered signal is calculated using a discrete differentiation of the filtered
- 20 data and re-filtered with a low-pass filter. These values are used in further calculations to determine if a T-wave is detected.
- In US-5,755,739 an adaptive and morphological system for
- 25 discriminating P-Waves and R-waves inside the human body is disclosed. A drawback of a system using morphological recognition is that it probably not is fast enough for real time operation and that it is often implemented by a microprocessor that has unacceptable high energy
- 30 consumption.
- In US-4,305,396 an improved automatically rate adaptive pacemaker is disclosed. The theory behind this patent is that a correlation has been identified between e.g. the
- 35 amplitudes of the R-wave and T-wave and the heart rate. This correlation is then used to control a rate-responsive pacemaker. The peak values of the QRS-wave and T-wave,

respectively, are detected in detection windows using conventional techniques. The detected values are then applied to a correlation block where a rate-controlling signal is generated.

5

One object of the present invention is to improve the safety in detecting electrical heart signals and to make it possible to determine the origin of detected signals. The heart stimulator according to the invention is in particular useful for a safe detection of premature ventricular contractions (PVCs).

10

Another object of the invention is to arrange an implantable heart stimulator having a detection of electrical heart signals that is fast and low energy consuming.

15

Short description of the inventive concept

The above objects are achieved by the invention in accordance with the characterizing portion of the appended main claim. Preferred embodiments are set forth in the dependent claims.

20

Short description of the appended drawings

25

Figure 1 shows an implantable heart stimulator. Figure 2 shows a block diagram of the implantable heart stimulating device according to the invention. Figure 3 shows a block diagram of a detection channel according to the invention. Figure 4 shows a block diagram of a preferred embodiment of a part of a detection channel according to the invention.

30

Detailed description of preferred embodiments of the invention

35

Figure 1 discloses an implantable heart stimulator comprising a heart stimulating device 2 and an electrode lead 4 inserted into the ventricle of a heart 6. The electrode lead is inserted into the heart and arranged in the ventricle according to procedures well known to persons skilled in the art. The heart stimulator disclosed in Fig. 1 relates to a single chamber heart stimulator, which means that the electrode lead is arranged in one chamber of the heart, in this case the right ventricle. However, it should be noted, that the invention is equally applicable in a dual chamber heart stimulator that comprises two heart electrode leads adapted to stimulate the heart both in the atrium and in the ventricle and also in a multi-chamber heart stimulator adapted to stimulate three or four chambers of the heart.

Figure 2 discloses the implantable heart stimulating device 2 according to the invention that comprises a pulse generator 8 for generating heart stimulating pulses to the heart via electrode lead 4. The heart stimulating device 2 further comprises a heart signal detecting means 10 connected to the electrode lead 4 and adapted to receive electrical heart signals 12 and to generate detected electrical heart signals 14 to three detection channels 16, 16', 16''. Each channel is adapted to generate a detection signal 18, 18', 18'' and a peak amplitude value 20, 20', 20'' to a heart event identifying means 22 that generates a signal 24 that identifies a detected heart event and applies said signal to a control means 26.

Figure 3 discloses one of the detection channels 16. The detection channel 16 comprises a filter means 28 that generates a filtered signal 30 that is applied to a threshold detector 32 and to a peak amplitude determining means 34. If the filtered signal exceeds a predetermined threshold 36 of said threshold detector 32 the detection

signal 18 is generated. The peak amplitude determining means 34 generates said peak amplitude value 20.

5 The invention is described in relation to a single chamber heart stimulator, i.e. with one electrode lead placed in the atrium or in the ventricle of the heart. As mentioned above the invention is equally applicable in a dual chamber heart stimulator where, for each electrode lead, a heart signal detection means and at least two detection channels are
10 associated.

Each filter means 28 has a predetermined filter characteristics, that differs from that of a filter means in another detection channel.

15 If the heart signal detection means 10 receives signals detected in the ventricle of the heart, the predetermined filter characteristics of the filter means in three parallel detection channels are e.g. tuned to be sensitive to R-waves, T-waves and PVCs, respectively.

20 The filter means sensitive to R-waves is a band-pass filter with a pass-band in the range 20-50 Hz.

The filter means sensitive to T-waves is a band-pass filter with a pass-band in the range 2-10 Hz.

25 And the filter means sensitive to PVCs is a band-pass filter with a pass-band typically in the range 15-40 Hz.

If the heart signal detection means 10 instead receives signals detected in the atrium of the heart, the predetermined filter characteristics of the filter means in
30 two parallel detection channels preferably are tuned to be sensitive to P-waves and far-field R-waves, respectively.

The filter means sensitive to P-waves is a band-pass filter with a narrow pass-band around 30 Hz.

35 The filter means sensitive to far-field R-waves is a band-pass filter with a pass-band typically in the range 10-35 Hz.

It is however possible to arrange further detection channels both for detection in the atrium and in the ventricle. E.g. to be able to detect different kinds of arrhythmia, states of atrial or ventricular fibrillation etc.

5

The filter means can be implemented using digital or analog filter techniques.

If a digital filter is used the analog detected heart signal is A/D converted before filtration is performed and the
10 processing of the filtered signal in the threshold detector and in the peak amplitude determining means is digital.

If an analog filter instead is used the above-mentioned processing might also be performed in an analog threshold
15 detector and in an analog peak amplitude determining means. As an alternative the filtered signal is A/D-converted after the filtration and then applied to the threshold detector and the peak amplitude determining means.

20 The filter characteristics discussed above could either be set at the manufacture of the implantable device or could be set by a physician during implantation of the device or later at a follow-up visit. The filter means could be automatically tuned by tuning means in the heart event
25 identifying means.

Figure 4 discloses a preferred embodiment of the threshold detector 32 and the peak amplitude determining means 34. The filtered signal 30 comprises a stream of digital bits
30 representing the heart signal. The bit-stream is applied to the threshold detector 32 which is a digital comparator with a threshold 36 that generates the detection signal 18 if the filtered signal exceeds said threshold. The detection signal is applied to the peak amplitude determining means 34 that,
35 according to this embodiment, is a shift register. When a detection signal is received by the determining means 34, the digital bit-stream is clocked into the shift register

during a predetermined time, about 10 - 30 ms. When the predetermined time has elapsed, the content of the shift register is inspected in order to find the maximum value and that value is then generated as the peak amplitude value 20.

- 5 According to another preferred embodiment of the invention the heart signal detection means receives signals detected in the ventricle of the heart. In figure 2 the detection channel 16 is tuned to be sensitive to R-waves, the
- 10 detection channel 16' is tuned to be sensitive to T-waves and the detection channel 16'' is tuned to be sensitive to PVCs. The detection channel 16 generates detection signal 18 (R_{det}), indicating a detected R-Wave, and a peak amplitude value 20 (R_{max}) indicating the peak amplitude of the detected
- 15 R-wave. According to the same principles T_{det} , T_{max} , PVC_{det} and PVC_{max} are generated by the detection channels 16', 16'', respectively.

- 20 The detection signals and the peak amplitude values are received by the heart event identifying means 22 where a number of heart event identifying criteria are applied.

To unequivocally identify an R-wave the following criteria must be fulfilled:

- 25 Detection signal R_{det} received, i.e. no T_{det} or PVC_{det} , and $R_{max}/PVC_{max} > 1$ (also $R_{max}/T_{max} > 1$ could be checked). The division R_{max}/PVC_{max} need only be performed if there also was a PVC_{det} .
- 30 $R_{max} - PVC_{max} > 0$ can be used instead of $R_{max}/PVC_{max} > 1$.

To unequivocally identify a PVC the following criteria must be fulfilled:

- Detection signal PVC_{det} received, i.e. no R_{det} or T_{det} and $PVC_{max}/R_{max} > 1$ and $PVC_{max}/T_{max} > 1$ if PVC_{det} and R_{det} .
- 35 The division PVC_{max}/R_{max} need only be performed if there also was an R_{det} .
- $PVC_{max} - R_{max} > 0$ can be used instead of $PVC_{max}/R_{max} > 1$.

Typical values for R_{\max} is in the range of 6-12 mV and for PVC_{\max} is in the range of 3-6 mV. T_{\max} has a maximal peak amplitude below 1 mV.

- 5 According to a second preferred embodiment of the invention the heart signal detection means receives signals detected in the atrium of the heart. In figure 2 only two detection channels are used and the detection channel 16 is tuned to be sensitive to P-waves and the detection channel 16' is
- 10 tuned to be sensitive to far field R-waves. The detection channel 16 generates detection signal 18 (P_{\det}), indicating a detected P-Wave, and a peak amplitude value 20 (P_{\max}) indicating the peak amplitude of the detected P-wave. According to the same principles $R(\text{far-field})_{\det}$ and $R(\text{far-field})_{\max}$ are generated by the detection channel 16'.
- 15

To unequivocally identify a P-wave the following criteria must be fulfilled:

- Detection signal P_{\det} received and $P_{\max} / R(\text{far-field})_{\max} > 1$ if
- 20 P_{\det} and $R(\text{far-field})_{\det}$.

To unequivocally identify a far-field R-wave the following criteria must be fulfilled:

- Detection signal $R(\text{far-field})_{\det}$ received and $R(\text{far-field})_{\max} / P_{\max} > 1$ if $R(\text{far-field})_{\det}$ and P_{\det} .
- 25

Typical values for P_{\max} when filtered with the P-wave adapted filter is in the range of 3-4 mV and when filtered with the far-field R-wave adapted filter in the range of 2-3 mV.

- 30 Typical values for $R(\text{far-field})_{\max}$ when filtered with the P-wave adapted filter is in the range of 2-3 mV and when filtered with the far-field R-wave adapted filter in the range of 3-4 mV.

- It should be noted that the individual variability regarding signal amplitudes may be significant.
- 35

The heart event identifying means 22 is implemented either by software in a microprocessor or by a digital network using commonly available programming technique or digital network design, respectively.

5

The filter means are continuously active which means that each filter means in each of the detection channels receives detected electrical heart signals and performs filtration during the whole heart cycle.

10 As soon as a detection signal is received by the heart event identifying means the peak amplitude values received during a predetermined time interval, e.g. from 0 to 30 ms, are used in the above-mentioned identifying criteria to identify the detected heart event.

15

The signal 24 identifying a detected heart event is applied to the control means 26 where appropriate action is taken in response of the detected heart event. That could be the reset of certain time intervals, the change of mode of operation for the heart stimulator and the adjustment of certain parameters, e.g. the sensitivity level. All this actions are well known to a person skilled in the art of heart stimulators and therefore not further described in the present application.

25

According to still another embodiment of the invention the heart event identifying means 22 is provided with means for tuning and adjusting the filter means to be more sensitive to the heart event it is intended to detect, e.g. R-waves.

30 That could be done by e.g. changing the band-width or another filter parameter of the filter.

In the embodiments of the invention described above the heart signal detection technique is only briefly discussed.

35 It should be noted that any detection technique resulting in a detection of heart signals is applicable in the present invention. The heart signal can be detected by a single

bipolar electrode lead by measuring between a tip and a ring electrode surfaces. If instead a unipolar heart electrode is used detection is performed between a tip electrode surface and an electrode surface at the pacemaker housing. Still
5 another possibility is to detect between electrode surfaces at different electrode leads that could be unipolar, bipolar or multipolar. The above-mentioned measurement techniques and expressions are well known to a person skilled in the art of heart stimulators and are therefore not further
10 described.

The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above
15 embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.

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Claims

1. Implantable heart stimulator comprising a heart signal detection means adapted to detect electrical heart signals and to apply said signals to at least two detection channels (16,16',16''), each channel comprises a filter means (28) with a predetermined filter characteristic, a threshold detector (32) with a predetermined threshold (36) and a peak amplitude determining means (34), wherein said filter means generates a filtered signal (30) that is applied to said threshold detector that generates a detection signal (18,18',18'') if said filtered signal exceeds said threshold and to said peak amplitude determining means that generates a peak amplitude value (20,20',20'') of said filtered signal **characterized in** that said heart stimulator further comprises a heart event identifying means (22) that unequivocally identifies, based on detection signals and peak amplitude values from different detection channels, a detected heart event.
2. Implantable heart stimulator according to claim 1 **characterized in** that said channels are continuously active.
3. Implantable heart stimulator according to any preceding claim **characterized in** that said identification is performed by applying predetermined heart event identifying criteria.
4. Implantable heart stimulator according to claim 3 **characterized in** that said identifying criteria include forming the quote and/or the difference between peak amplitude values provided that at least one detection signal is received by the heart event identifying means.
5. Implantable heart stimulator according to any preceding claim **characterized in** that said predetermined filter characteristics for filter means in different detection channels are tuned to be sensitive to R-waves, T-waves and

PVCs, respectively.

6. Implantable heart stimulator according to any of claims 1-4 **characterized in** that said predetermined filter characteristics for filter means in different detection channels are tuned to be sensitive to P-waves and far-field R-waves, respectively.
7. Implantable heart stimulator according to any preceding claim **characterized in** that said heart event identifying means comprises tuning means adapted to tune said filter means.
8. Implantable heart stimulator according to any preceding claim **characterized in** that said detected heart event could be any of the following: an R-wave, a T-wave, a PVC, a P-wave or a far-field R-wave.

Abstract

Implantable heart stimulator comprising a heart signal
detection means (10) adapted to detect electrical heart
5 signals (12) and to apply said signals to at least two
detection channels (16,16',16''), each channel comprises a
filter means with a predetermined filter characteristics, a
threshold detector with a predetermined threshold and a peak
amplitude determining means. Each channel is adapted to
10 generate a detection signal and a peak amplitude value. The
heart stimulator further comprises a heart event identifying
means (22) that unequivocally identifies, based on said
detection signals and said peak amplitude values, a detected
heart event. Applying predetermined identifying criteria,
15 e.g. by forming the difference and/or the quote between the
peak amplitude values performs said identification.

(Figure 2)

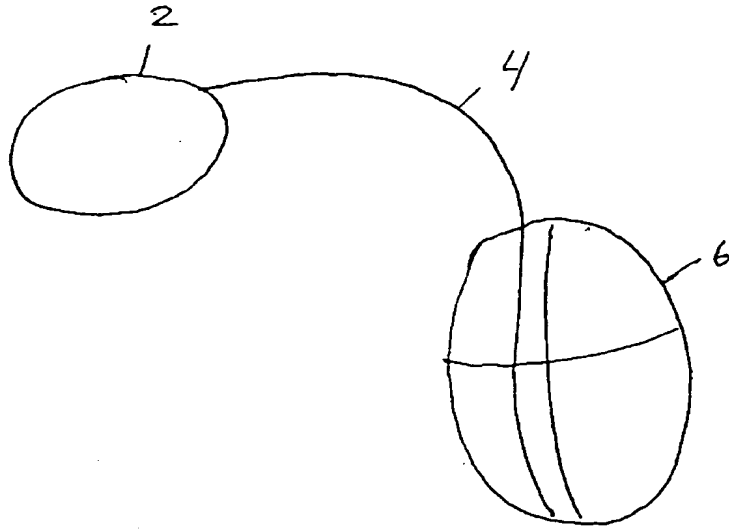


fig. 1

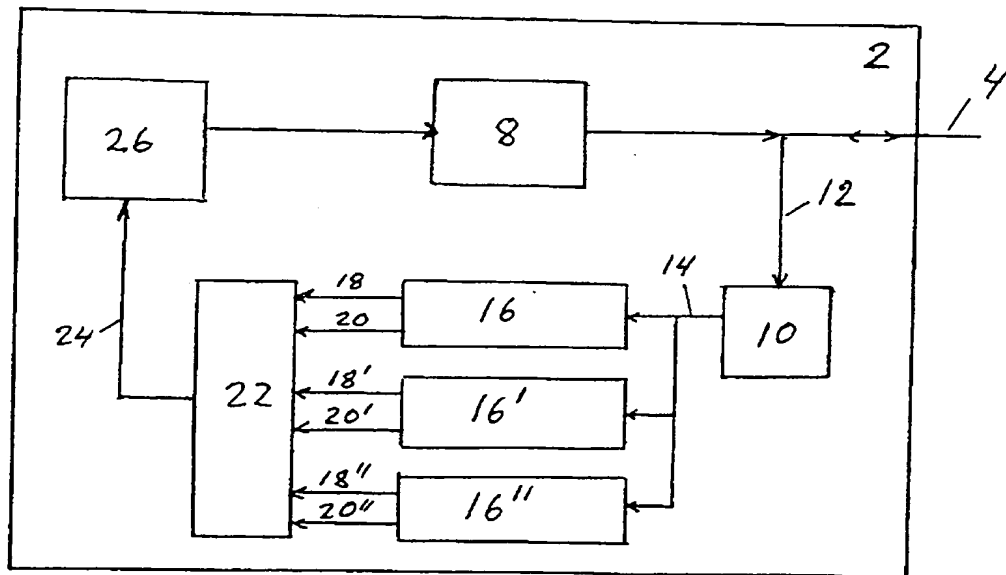


fig. 2

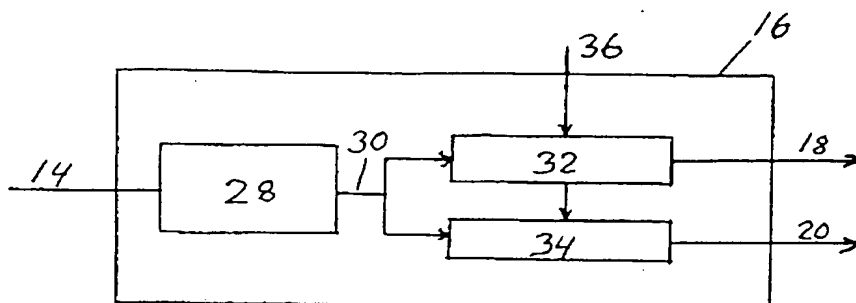


fig. 3

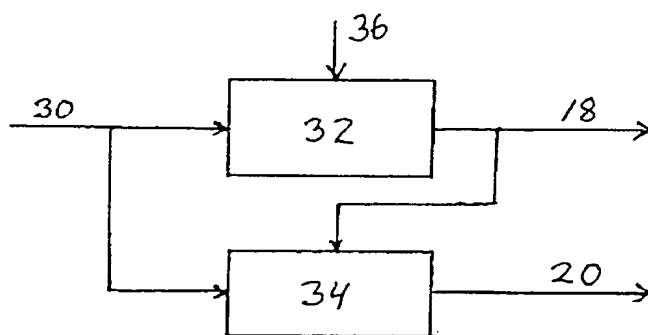


fig. 4